From: Vandenberg, John [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCAE2B98A04540FB8D099F9D4DEAD690-VANDENBERG, JOHN]

**Sent**: 4/30/2011 6:21:13 PM

To: Flowers, Lynn [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=1a4411c874d041b9a8badfc32b91bd70-Flowers, Lynn]

CC: Clark, Becki [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=a906e07f1cd143b9a3c2ddab813b8140-Clark, Becki]; Winner, Darrell

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=860556f5cd0f4855839907bcc90b2c41-Winner, Darrell]; Cogliano, Vincent

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=51f2736376ac4d32bad2fe7cfef2886b-Cogliano, Vincent]

Subject: Re: 3 Parts re Methanol Letter 1) draft response to Maria Hegsted, 2) my call with George Cruzan, and 3) J Gift

evaluation re Methanol Institute Letter

### Also, the arsenic response was Greatly appreciated!

\_\_\_\_\_

### Sent by EPA Wireless E-Mail Services

---- Original Message -----

From: John Vandenberg

**Sent:** 04/30/2011 02:20 PM EDT

To: Lynn Flowers

Cc: Becki Clark; Darrell Winner; Vincent Cogliano

Subject: Re: 3 Parts re Methanol Letter 1) draft response to Maria Hegsted, 2) my call

with George Cruzan, and 3) J Gift evaluation re Methanol Institute Letter

### Vine had some similar thoughts.

\_\_\_\_\_

### Sent by EPA Wireless E-Mail Services

---- Original Message -----

From: Lynn Flowers

Sent: 04/30/2011 01:42 PM EDT

To: John Vandenberg

Cc: Becki Clark; Darrell Winner

Subject: Re: 3 Parts re Methanol Letter 1) draft response to Maria Hegsted, 2) my call

with George Cruzan, and 3) J Gift evaluation re Methanol Institute Letter

# **Deliberative Process / Ex. 5**

### Sent by EPA Wireless E-Mail Services

---- Original Message -----

From: John Vandenberg

**Sent:** 04/29/2011 12:35 PM EDT

To: Lynn Flowers

Cc: Becki Clark; Darrell Winner

Subject: Fw: 3 Parts re Methanol Letter 1) draft response to Maria Hegsted, 2) my call

with George Cruzan, and 3) J Gift evaluation re Methanol Institute Letter

FYI - nothing big here.

John Vandenberg, PhD

Director, RTP Division National Center for Environmental Assessment B243-01 Office of Research and Development, USEPA Research Triangle Park, NC 27711

Tel: 919 541 4527 Fax: 919 541 5078

---- Forwarded by John Vandenberg/RTP/USEPA/US on 04/29/2011 12:35 PM ----

From: Jeff Gift/RTP/USEPA/US

To: John Vandenberg/RTP/USEPA/US@EPA

Cc: Debra Walsh/RTP/USEPA/US@EPA, Reeder Sams/RTP/USEPA/US@EPA, Stan Barone/RTP/USEPA/US@EPA,

Jeff Gift/RTP/USEPA/US@EPA, JMichael Davis/RTP/USEPA/US@EPA, John Rogers/RTP/USEPA/US@EPA, Reeder Sams/RTP/USEPA/US@EPA, Paul Schlosser/RTP/USEPA/US@EPA, Allen Davis/RTP/USEPA/US@EPA

Date: 04/29/2011 12:31 PM

Subject: Re: Fw: 3 Parts re Methanol Letter 1) draft response to Maria Hegsted, 2) my call with George Cruzan, and 3) J Gift

evaluation re Methanol Institute Letter

John et al.,

# **Deliberative Process / Ex. 5**

[attachment "McCallum2011.pdf" deleted by Lynn Flowers/DC/USEPA/US] [attachment "Sweeting2010.pdf" deleted by Lynn Flowers/DC/USEPA/US] Jeff Gift, Ph.D.
National Center for Environmental Assessment EPA (B243-01)
RTP, NC 27711
919-541-4828
919-541-0245 (fax)
gift.jeff@epa.gov

From: John Vandenberg/RTP/USEPA/US

To: Jeff Gift/RTP/USEPA/US@EPA, Reeder Sams/RTP/USEPA/US@EPA, Debra Walsh/RTP/USEPA/US@EPA

Date: 04/29/2011 12:07 PM

Subject: Fw: 3 Parts re Methanol Letter 1) draft response to Maria Hegsted, 2) my call with George Cruzan, and 3) J Gift

evaluation re Methanol Institute Letter

FYI and Jeff, please note Lynn's comment. Any thoughts on this?

John Vandenberg, PhD
Director, RTP Division
National Center for Environmental Assessment B243-01
Office of Research and Development, USEPA
Research Triangle Park, NC 27711

Tel: 919 541 4527 Fax: 919 541 5078

---- Forwarded by John Vandenberg/RTP/USEPA/US on 04/29/2011 12:08 PM ----

From: Lynn Flowers/DC/USEPA/US

To: John Vandenberg/RTP/USEPA/US@EPA

Co: Audrey Hoffer/DC/USEPA/US@EPA, Becki Clark/DC/USEPA/US@EPA, Darrell Winner/DC/USEPA/US@EPA

Date: 04/29/2011 11:52 AM

Subject: Re: 3 Parts re Methanol Letter 1) draft response to Maria Hegsted, 2) my call with George Cruzan, and 3) J Gift

evaluation re Methanol Institute Letter

# **Deliberative Process / Ex. 5**

Lynn

Lynn Flowers, PhD, DABT
Acting Associate Director for Health
National Center for Environmental Assessment
Office of Research and Development
U.S. EPA

Mailing address:

1200 Pennsylvania Ave., NW (8601P)

Washington, DC 20460 Phone: 703-347-8537 FAX: 703-347-8699

Physical location:

Two Potomac Yard (North Building) 2733 S. Crystal Drive Arlington, VA 22202

From: John Vandenberg/RTP/USEPA/US

To: Becki Clark/DC/USEPA/US@EPA, Darrell Winner/DC/USEPA/US@EPA, Lynn Flowers/DC/USEPA/US@EPA,

Audrey Hoffer/DC/USEPA/US@EPA

Date: 04/29/2011 11:45 AM

Subject: 3 Parts re Methanol Letter 1) draft response to Maria Hegsted, 2) my call with George Cruzan, and 3) J Gift

evaluation re Methanol Institute Letter

I put relevant information together in one email to make it easier to see the parts. Please let me know if any questions, and also need feedback re Part 1.

## Part 1)

Audrey sent me this late yesterday. My draft response in Blue. Let me know of edits, deadline is 10 am Monday

From: Mollie Lemon/DC/USEPA/US

To: Carolyn Hubbard/DC/USEPA/US@EPA
Cc: Megan Maguire/DC/USEPA/US@EPA

Date: 04/28/2011 03:55 PM

Subject: ACTION: Inside EPA q's on non-cancer IRIS assessment on methanol (deadline: 10 am 5/2)

Hi all--a few questions from Maria Hegsted at Inside EPA. Can we try to respond? Thanks!!

I've a few questions regarding the draft non-cancer IRIS assessment methanol that was released last week.

1. The non-cancer assessment appears similar, if not the same, as the non-cancer section of the January 2010 draft IRIS assessment. Were substantive changes made between the two versions? Response: The 2011 draft IRIS non-cancer assessment for methanol contains the same information, analyses and conclusions—related to non-cancer outcomes as was included in the 2010 draft IRIS assessment for methanol. The following information was provided in the Federal Register notice at the time of public release of the 2010 draft (bold emphasis added):

In January 2010, EPA released an external peer review draft IRIS

Toxicological Review for methanol (EPA/635/R-09/013), containing both cancer and non-cancer analyses, and requested that the Science Advisory Board conduct a review of this human health assessment. Following a report from the National Toxicology Program, EPA placed the external peer review of the draft IRIS Methanol Toxicological Review on hold. The National Toxicology Program report recommended that pathology reviews be carried out to resolve differences of opinion in the diagnoses of certain tumors reported in a Ramazzini Institute methanol research study, which was cited and used to support some of the conclusions in the draft IRIS assessment. As a result, EPA and the National Institute of Environmental Health Sciences plan to jointly sponsor an independent Pathology Working Group (PWG) review of select studies conducted at the Institute. EPA is today releasing the draft IRIS Methanol Toxicological Review (Non-Cancer) for public comment while continuing to hold the cancer assessment that was previously released in January 2010. The data and studies used in the draft IRIS Methanol Toxicological Review (Non-Cancer) are unrelated to the tumor diagnoses being re-examined by the PWG. The information, analyses and conclusions of the draft assessment announced in this notice are identical to the non-cancer portions of the draft assessment previously released in January 2010. Comments relevant to the non-cancer methanol assessment that were received during the previous public comment period for the joint cancer and non-cancer assessment will be considered along with new comments.

- 2. Was a search conducted for new literature prior to releasing the new non-cancer methanol document? What was the criteria for adding new studies (if any) to the assessment? Response: EPA is continually identifying new literature related to the health assessment of methanol; as noted in response to Question 1, the information, analyses and conclusions of the 2011 draft are identical to the non-cancer portions of the draft previously released in January 2010 hence no new studies were added.
- 3. Did EPA review the methanol-industry funded research performed at the University of Toronto (Sweeting et al and McCallum et al, both 2010) before releasing the new methanol document? Why isn't it referenced in the draft document? See response to guestions 1 and 2.

### Part 2:

# **Deliberative Process / Ex. 5**

# **Deliberative Process / Ex. 5**

John

### Part 3:

Email from Jeff Gift to Methanol team providing his take on MI comments;

From: Jeff Gift/RTP/USEPA/US

To: Stan Barone/RTP/USEPA/US@EPA, Jeff Gift/RTP/USEPA/US@EPA, JMichael Davis/RTP/USEPA/US@EPA, John

Rogers/RTP/USEPA/US@EPA, Reeder Sams/RTP/USEPA/US@EPA, Paul Schlosser/RTP/USEPA/US@EPA, Allen

Davis/RTP/USEPA/US@EPA

ିର: John Vandenberg/RTP/USEPA/US@EPA, Debra Walsh/RTP/USEPA/US@EPA

Date: 04/29/2011 10:28 AM

Subject: Fw: Methanol Institute Letter on Methanol Noncancer Assessment

Methanol Team,

# Deliberative Process / Ex. 5

# **Deliberative Process / Ex. 5**

I will try to keep you informed on what develops as a result of this.

Regards,

Jeff

Jeff Gift, Ph.D.
National Center for Environmental Assessment
EPA (B243-01)
RTP, NC 27711
919-541-4828
919-541-0245 (fax)
gift.jeff@epa.gov

---- Forwarded by Jeff Gift/RTP/USEPA/US on 04/29/2011 09:24 AM ----

From: Greg Dolan <gdolan@methanol.org>
To: Paul Anastas/DC/USEPA/US@EPA

Cc: Kevin Teichman/DC/USEPA/US@EPA, Jeff Gift/RTP/USEPA/US@EPA, Becki Clark/DC/USEPA/US@EPA, Desk

IRIS@EPA, Bernard King/DC/USEPA/US@EPA, Vincent Cogliano/DC/USEPA/US@EPA

Date: 04/28/2011 04:48 PM

Subject: Methanol Institute Letter on Methanol Noncancer Assessment

### Dear Dr. Anastas:

Attached is a letter from the Methanol Institute requesting that you withdraw the noncancer IRIS assessment of methanol from its current public and peer review cycle. In our view, the current assessment is so fundamentally flawed that to proceed with peer review of the document would be meaningless, and in fact, counterproductive to good scientific process. We realize that your office often receives requests to delay or re-do your IRIS assessments, so the attached letter explains why we believe that developments since the initial draft was released in December 2009 fundamentally undermine the core elements of the current assessment and therefore necessitate a re-working NOW of the assessment rather than later after peer review.

We would like to meet with you do discuss this request in more detail, and will call your office in a few days to seek a mutually satisfactory time for such a meeting.

Gregory Dolan
Executive Director, Americas/Europe
Methanol Institute
124 South West Street, Suite 203
Alexandria, VA 22314
gdolan@methanol.org
(703) 248-3636

[attachment "MI Letter to Dr Anastas on Methanol Noncancer Assessment.pdf" deleted by Jeff Gift/RTP/USEPA/US]